bioproduction

thermoscientific



Flexible, reliable, and configurable bioprocessing solutions

For process development and production operations



Single-use bioprocessing equipment

Speed to market and risk mitigation are top customer concerns, and Thermo Fisher Scientific offers expertise and solutions to address these concerns seamlessly. We manufacture single-use equipment to facilitate integration and customization across upstream and downstream bioprocessing workflows. Our controls and hardware, utilizing DeltaV[™] data management solutions from Emerson, create flexible operating systems with the integration of modular hardware, novel single-use sensors, and state-of-the-art bioreactors for strategic and streamlined bioprocess control.

You can now easily configure and standardize processes that employ Thermo Scientific[™] HyPerforma[™] Single-Use Bioreactors (S.U.B.s), Single-Use Fermentors (S.U.F.s), Single-Use Mixers (S.U.M.s), BioProcess Containers (BPCs), automation platforms, and other accessories for rapid scaleup—from process development to commercial manufacturing.

Benefits of single-use equipment and automation

- Quality and flexibility—innovative hardware and automation systems designed for ease of use and integration
- Efficiency in design—components are designed to be ergonomic, scalable, compact, and easily configurable
- Adaptability and choice—hardware and software platforms are available for ready assembly or for preconfigured, turnkey operation
- Knowledgeable and comprehensive support extensive documentation and global, field-based technical support



TruBio Bioprocess Control Software

Automation software and control platforms

The technology and data transfer during the lifecycle of drug development, from bench-scale laboratory applications to large-scale production, is often challenging and time consuming, and involves many different user requirements. Thermo Scientific[™] TruBio[™] Bioprocess Automation and Control Software improves tech transfer time and validation costs by running on a consistent data model from R&D to commercial production. With TruBio software being powered by the DeltaV[™] Discovery platform at lab scale and DeltaV Distributed Control platform at pilot, clinical, and production scales (both platforms from Emerson), considerable savings are achievable in risk mitigation, including reduced training and validation costs. Standardizing with open-architecture controllers simplifies data transfer and storage, which can result in introducing new products to market faster.



For research and process development solutions

The TruBio Discovery software platform provides a simplified solution to meet the needs of research and process development labs. This software platform provides the benefits of transferring to processes that require a higher level of qualification and control. A single, workstation-based controller is utilized to execute process control strategies.



For production-scale solutions TruBio software with the DeltaV

platform and the Thermo Scientific[™] TruLogic[™] controller provide flexible and reliable state-of-the-art control capability. With multiple sensor loops as well as gas and liquid addition capabilities, this software can be used with both HyPerforma (S.U.B.s, S.U.F.s, S.U.M.s), and other thirdparty bioreactors to provide a process control platform from research through commercial manufacturing.



For downstream solutions

Based on the same robust, validated platform as TruBio software, Thermo Scientific[™] TruChrom[™] and TruPur[™] customizable software platforms are designed specifically to control common third-party chromatography and purification skids. This allows for integration and control of downstream processes to help ensure transferability of data throughout the workflow.

TruBio Bioprocess Control Software

For production-scale solutions

TruBio Bioprocess Automation and Control Software for production-scale solutions provides easy-to-use process control. It can be configured by the user through a visual interface, eliminating the need to know process control programming. TruBio software is powered by a DeltaV system from Emerson, has been developed according to GAMP[™] 5 methods, and conforms to regulatory requirements for use in cGMP-compliant processes.

Developed for use with HyPerforma controllers, TruBio software is designed to support easy scaling of tech transfer, reducing the time required for validation services. It enables the user to build sophisticated process control strategies without knowledge of DeltaV programming. It allows dynamic linking of interlocks and remote setpoints without the need for a software download. Calibration of multiple devices can be performed at the same time. It also provides the flexibility to incorporate a wide range of cell culture, fermentor, or mixing vessels and manage multiple data streams from several unit operations.

TruBio software features

- Vessel key parameters displayed on overview graphic
- User interface provides display of setpoint (SP), outputs, and process value (PV) of all connected sensors
- Can create simple and complex control strategies from the user interface
- Auto-detection of internal pumps and Thermo Scientific[™] TruFlow[™] mass flow controllers (MFCs)
- Can calibrate multiple devices at the same time, even for analog devices
- Allows dynamic linking of interlocks and remote setpoints without the need for a software download
- Can save and load vessel configuration
- Pump dosing options: pump dose, ramp, bolus



- Can load the same vessel configuration to other vessels that have the same model of G3 controller
- Auxiliary control modules allow connection and control of external analog devices
- Full record and display of the last vessel process information, including SPs
- Option to load previously defined vessel process parameters
- 21 CFR Part 11 compliance
- Event chronicle
- Interlock configurations
- Process data storage
 - Continuous historian
 - Audit trail
 - Alarm and events

TruBio software capabilities

Basic operations

- Key parameter display on configuration page
- Analyzer data entry pages
- Vessel settings

- Backup and restore procedures
- User access configuration
- Online parameter updates
- 21 CFR Part 11 compliance

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Software capabilities					
Process controllers for: • pH*	Calibrations ● pH				
• Dissolved oxygen (DO)*	• DO				
Vessel weight	• Temperature				
Agitator	Pressure				
• Gas flow	Agitator speed				
 Vent filter heater control (HyPerforma G3Lite and G3Pro controllers) Auxiliary analog equipment Pump dosing options: pump dose, ramp, bolus 	Vessel weight: zero, tareAuxiliary input				
Supported communication interfaces					
• OPC UA/OPC DA	Serial Modbus RTU				
• OPC A&E/OPC HDA	Profibus DP				
	 Modbus TCP (with DeltaV[™] PK Controller) 				
Options					
Compatible with DeltaV Configuration Audit Trail (VCAT)Addition of DeltaV Batch for recipe creation	 Have standard batch and non-batch templates for Dream Report software Unique multi-feed scale option (tracks up to four feeds on one scale to save cost and space) 				
Works with DeltaV Mobile and ControlSee for mobile alerts					

* Each parameter can control up to 4 separate devices (i.e. pumps and MFC devices).

HyPerforma G3Lite Controller

The Thermo Scientific[™] HyPerforma[™] G3Lite[™] Bioprocess Controller is an open-architecture control system that can be integrated with most S.U.B.s and S.U.F.s. The system consists of a control tower that leverages intelligent transmitters, MFCs, pumps, sensors, and TruBio software that facilitates easy, reliable, and repeatable process development and commercial cell culture processes. HyPerforma G3Lite Controllers are fully self-contained, movable units that can be operated alone (for one vessel) or networked for multiple vessels. They are engineered to optimize capital cost for use in non-GMP and cGMP-certified production facilities.

Key features

- Scalability—transfer any process from 30 L to 2,000 L
- Modularity-predefined configurations available for 50, 100, 250, 500, 1,000, and 2,000 L bioreactors and 30 and 300 L fermentors
- Touchscreen interface for easy data entry and control
- Stand-alone or networked (for multiple vessels)—enabled by distribution control system (DCS)
- Flexible upstream TruBio software powered by the DeltaV system from Emerson
- Includes up to six MFCs with air, O₂, N₂, CO₂ for drilled-hole spargers (DHS) and cross-flow filtration



HyPerforma G3Lite Bioprocess	Controller specifications			
Cart dimensions (H x W x D)	160 x 68 x 54 cm (63 x 27 x 21 in.)			
Enclosure rating	Cart: NEMA 12/IP52, HMI-NEMA 4X			
Operating temperature	5°C to 40°C (41°F to 104°F)			
Storage temperature	–40°C to 70°C (–40°F to 158°F)			
Relative humidity	5% to 95% (noncondensing)			
Certifications	CE specifications EN-60101 and EN-61325			
Weight/shipping weight	68 kg/136 kg (150 lb/300 lb)			
рН	PendoTECH [™] Transmitter (electrochemical), pH transmitter (single-use)			
DO	PendoTECH Transmitter (electrochemical), DO transmitter (single-use)			
Temperature	Transmitter (RTD)			
Pressure	Transmitter			
Load cells*	Transmitter (vessel has built-in load cells)			
Foam level	Transmitter and cable assembly			
Agitator	Variable frequency drive (VFD) included to control agitator motor			
* Please refer to the HyPerforma S.U.B and S.U.F. literatu	re for more information on load cells.			

HyPerforma G3Pro Controller

The Thermo Scientific[™] HyPerforma[™] G3Pro[™] Bioprocess Controller has many of the capabilities of the HyPerforma G3Lite Bioprocess Controller and also enables an additional layer of versatility by allowing mobility and flexibility in terms of any reconfiguration and application expansion.

Key features

- Open-architecture capabilities to integrate with vessels from other suppliers
- Scalability that allows transfer of any process from 30 L to 2,000 L
- Adaptable for multi-product applications and to fit individual process needs
- Redundant sensor control mechanism, built-in circuit for optional stack light, and alarm relay for building alarm
- Probe configuration options that are flexible to connect electrochemical, single-use, or both types for pH and DO measurements
- Utilizes TruBio Bioprocess Automation and Control Software powered by the DeltaV platform with a touchscreen NEMA interface for data entry and control
- 8 additional analog input connectors (4–20 mA) plus 4 auxiliary control loop connectors (4–20 mA) for system expansion capability

HyPerforma G3Pro Bioprocess Controller specifications					
Utility cart dimensions (H x W x D)	914.4 x 609.6 x 228.6 mm (36 x 24 x 9 in.)				
Enclosure rating	NEMA 12/IP56 Touchscreen control box: NEMA 4X				
Operating temperature	5°C to 40°C (41°F to 104°F)				
Storage temperature	–25°C to 85°C (–13°F to 185°F)				
Relative humidity	5% to 95% (noncondensing)				
Weight/shipping weight	18 kg/41 kg (40 lb/90 lb)				
Control cart weight/ shipping weight	75 kg (165 lb)/120 kg (265 lb)				
pH (up to 3 available)	Thermo Scientific [™] TruSens [™] Transmitter (electrochemical mV), 2 included as standard for redundancy, third is optional				
DO (up to 3 available)	TruSens Transmitter (electrochemical nA), 2 included as standard for redundancy, third is optional				
Temperature (up to 2)	TruSens Transmitter (RTD), 1 included as standard				
Pressure (up to 2)	PendoTECH [™] PT-10, 1 included as standard				
Liquid control	4 variable-speed Watson-Marlow [™] peristaltic pumps				

Pump head options	Watson-Marlow [∞] 114, 313, or 520 series
Gas controlTruFlow MFC: Option of up to 6 MFCs (up to gas inlets and 3 gas outlets) Options of high flow and very high flow rates available up to 600 L/min on separate mani	
Scales/ balances	Al x 4 available for digital scales via Profibus (analog optional)
Inputs/outputs	Al x 4 (0–20 mA, 16-bit resolution) (24 V DC, PV) Al x 4 (0–20 mA, 12-bit resolution) (24 V DC, PV) AUX x 4 (0–20 mA, 12-bit resolution) (SP, PV)
Thermal control Thermal control unit (TCU) for jacketed vessel and optional heated S.U.B.	
External pumps	In addition to the pumps on the cart, additional external pumps can be mounted on a pump tower, and optional analog controlled case pumps
Agitator	Vessel adapter box (VAB) with variable frequency drive (VFD) supplied for HyPerforma and third-party vessels
Alarm	Alarm relay for building alarm, optional stack light circuitry (must order stack light separately)
Vent filter heater	Option to control 2 or 4 vent filter heaters



TruFlow Gas Mass Flow Controller

For HyPerforma G3Lite and G3Pro Controllers

The TruFlow Gas Mass Flow Controller (MFC) is designed to work with all of the HyPerforma bioreactor control systems. Its compact assembly provides up to six standard mass flow controllers and three associated solenoid valves. When connected, the TruFlow Gas MFC is instantly recognized by TruBio software to provide precise control of gas flow, without requiring any configuration, even at extremely low flow rates.

TruFlow Gas MFC key features

- Variety of flow rate options*
- Flow range configurability
- Plug-and-play connectivity

TruFlow gas MFC specifications



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Enclosure dimensions (H x W x D)	Six mass flow controllers: 9.1 x 7.4 x 6.2 in.
Rating	NEMA 1, IP 51 (liquid wipedown), options of high flow and very high flow rates available up to 600 L/min on separate manifold
Maximum gas flow rate	Configurable up to 50 L/min*
Weight/shipping weight	5.8 kg/9.1 kg (12.8 lb/20 lb)
Operating temperature	5°C to 40°C (41°F to 104°F)
Storage temperature	-40°C to 70°C (-40°F to 158°F)
Relative humidity	5% to 95% (noncondensing)
Certifications	CE: EN-61326 and EN-61010
Inlet pressure	1.6 to 2.3 bar/25 to 35 psig
Outlet pressure	0 to 1.38 bar/0 to 20 psig
Accuracy	±0.8% of flow rate and ±0.3% full scale (Burkert)
Repeatability	±0.1% full scale (Burkert)
Cable assembly	2 m (6 ft) standard

Suggested range of operating parameters																		
Volume	50 L		100 L			250 L			500 L			1,000 L			2,000 L			
Recommended maximum gas flow rates (slpm)	DHS	Cross- flow	Overlay	DHS	Cross- flow	Overlay	DHS	Cross- flow	Overlay	DHS	Cross- flow	Overlay	DHS	Cross- flow	Overlay	DHS	Cross- flow	Overlay
Air	5	5	5	10	9	9	25	13	13	50	25	25	100	40	40	200	60	60
0 ₂	5	-	_	10	-	_	25	-	-	50	-	-	100	-	_	200	-	-
CO2	1	-	_	2	-	-	2	-	-	2	-	-	5	-	_	5	-	_
N ₂	1	-	_	2	-	_	5	-	-	5	-	-	10	-	_	10	-	-
Total	5	5	5	10	9	9	25	13	13	50	25	25	100	40	40	200	60	60
Exhaust load		20			20			90			90			180			360	

Note: Due to size, MFCs higher than 50 LPM require different housing than represented in photo.

* May require additional configuration for specific flow rate. Please consult with your local sales representative for more information.



Sensors for superior process control

Single-use and reusable sensors

Thermo Fisher Scientific offers best-in-class single-use and reusable sensors for the measurement of pH, dissolved oxygen, biomass, and headspace pressure—with high reliability and superior performance for cell culture and fermentation process monitoring to meet all of your process analytical technology (PAT) needs.

To further enhance your processes, digital integration is possible with the use of our bioprocess controllers paired with TruBio Bioprocess Automation and Control Software. We offer a range of intuitive process sensors whether you're incorporating them into a single-use bioprocess container or an autoclavable vessel process—to help you monitor processes, reduce failures, and gain efficiencies.



TruSens Transmitter Blade

The Thermo Scientific[™] TruSens[™] Transmitter Blade is a combined technology designed to monitor all conventional pH and dissolved oxygen (DO) sensors. It allows the connection of a resistance temperature detector (RTD) or a thermistor inputs to suit the user's preferred sensor technology in upstream processes.

This transmitter blade with TruBio software allows for temperature compensation and is compatible with electrochemical sensors and digital sensors that output nAmp or mV signals.

Features

Compatible with most sing	gle-use or reusable sensors
Designed to easily integra Control software	te with TruBio Bioprocess
Easily incorporated into th Bioprocess Controllers	ie Thermo Scientific™
• Minimal maintenance	
TruSens Transmitter Blade	specifications
Physical	
Case material	Aluminum bracket
Dimensions (H x W x D)	130 x 35 x 128 mm (5.1 x 1.4 x 5.0 in.)
Weight/shipping weight	0.1/0.3 kg (0.2/0.6 lb)
Mounting	Enclosure mounted within utility tower
Display	TruBio Bioprocess Control Software (GAMP5)
RFI/EMI	EN 61326-1
Operating temperature	5°C to 45°C (41°F to 113°F) ambient
Storage temperature	0°C to 65°C (32°F to 149°F)
Relative humidity	10% to 90% (noncondensing)
Electrical	
Power supply	24 VDC @ 150 mA
Signal outputs*	6 analog 4–20 mA (1 electrochemical pH, 1 electrochemical DO, 2 PT100 RTD, 2 thermistor)
Signal inputs	pH (–520 mV to 520 mV), DO (0–500 nA) , PT100 RTD (0–100°C), thermistor (0–100°C for 10 kΩ, 15–130°C for 22 kΩ)
Output accuracy	Analog: ±0.1 mA Digital: NA

* If a sensor loop is activated but no sensors are attached, the following errors will be seen: the DO current will drop and produce a low "%SAT" reading, the pH will be unstable and indeterminate, RTD channels will read maximum temperature, and the thermistor channels will read minimum temperature.



Superior, proprietary pump technology

Outstanding precision for dosing, feeding, mixing, transferring, or harvesting

Our pumps have been designed to meet high-precision liquid delivery requirements in upstream (with controller) and downstream (external pumps) bioprocess applications. The pumps combine industry-known Watson-Marlow[™] pump heads with electronic boards. This pairing enables optimized control of dosing, feeding, product transfer/ harvest, buffer mixing (gradient or step), or general liquid management.

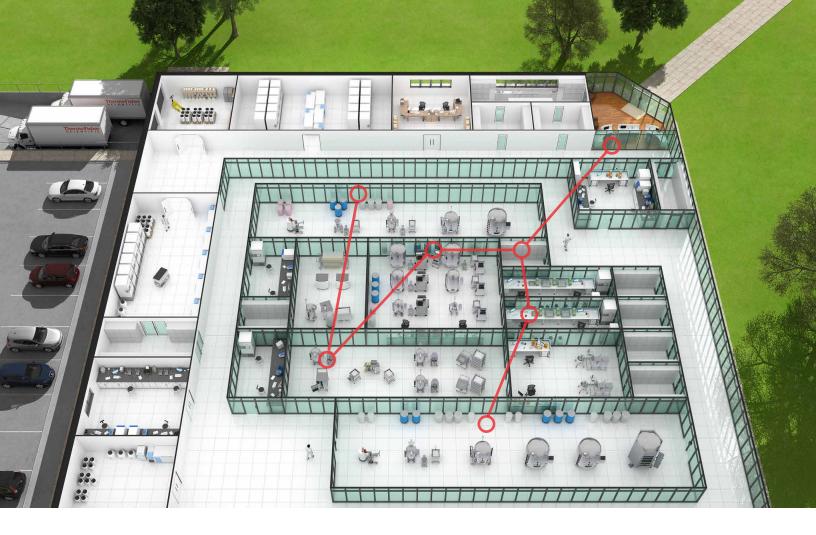
• Auto-detection of the pump by the TruBio software



Unleash your controller

These pumps are standard in the G3 controller family and can be interchanged if the process flow rate requirements change or if the controller is used with a different size or type of vessel. In G3 controllers, all pump communication is aggregated by a master communication board; this board reads process values from and sends instructions to the pumps.

Pump specifications									
Pump series	114	313	520						
Power supply	24 V DC	24 V DC	24 V DC						
Max. current (at 25°C)	0.25 A	0.95 A	1.5 A						
Average current (at 25°C)	0.2 A 0.75 A 1 A								
Operating temperature	5°C to 50°C (41°F to 122°F)								
Storage temperature	-10°C to 70°C (14°F to 158°F)								
Humidity	10% to 90% (noncondensing)								
Speed	5 to 160 rpm	1 to 300 rpm	1 to 300 rpm						
Accuracy	± 2 rpm, or $\pm 2\%$ of set point	±1 rpm, or ±2% of set point	±1 rpm, or ±2% of set point						
Certifications	CE: EN-60101 and EN-61326	CE: EN-60101 and EN-61326	CE: EN-60101 and EN-61326						
Tubing (thickness, ID)	0.8 mm, 4.8 mm	0.8 mm, 8.0 mm	1.6 mm, 9.6 mm						



Consistent, accurate data management

Consistent, accurate data management plays an important role for organizations and individuals in bioprocessing process development and scale-up. Dedicated data management platforms and automation solutions are a vital components of data governance. We offer flexible TruBio software solutions powered by DeltaV distributed control platforms from Emerson—to help manage your mammalian cell culture and microbial fermentation processes. Robust data management can mitigate risks during all stages in biopharmaceutical scale-up. Efficient, process-specific measurement of critical parameters as well as the aggregation of the data enables you to get your final product to market quickly. We help you so that you can focus on your process optimization and scale-up, rather than worry about the software tools needed to get you there.

Find out more at thermofisher.com/productionsolutions



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